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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,055	08/08/2001	Wayne R. Kindsvogel	00-56	2607

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ZymoGenetics, Inc.
1201 Eastlake Avenue East
Seattle, WA 98102

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,055

Applicant(s)

KINDSVOGEL ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 39-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 39-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in the response filed 7 July 2003 is acknowledged. The traversal is on the ground(s) that a claim was omitted from Group II. Claim 38 should have been placed in Group I, as a method of expressing the polynucleotide. However, this claim has now been cancelled. The requirement is thus still deemed proper and is therefore made FINAL. Claims 1-24 and 39-66 are pending in this application; claims 1-24 and 39-42 are withdrawn from consideration as being drawn to a non-elected invention. It is noted that the claim listing of 7 July 2003 omits those claims still present in the application but withdrawn from consideration, which is improper under current rules.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 61-66 are rejected under 35 U.S.C. 102(a) and 102(e) as being anticipated by U.S. patent 5,965,704 (Lok et al., 1999).

The '704 patent teaches a protein of residues 18-228 of SEQ ID NO: 2 that is identical to instant SEQ ID NO: 3 in column 1, line 32 and claim 1, column 29. Fc fusions and other modifications are taught in column 2, lines 23-28, and column 14, lines 10-41. The properties of forming a monomeric or homodimeric receptor, and the ability to bind IL-TIF, are inherent to the protein.

4. Claims 61-66 are also rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/07848 (Lok et al., 1999).

WO 99/07848 also teaches a protein of residues 18-228 of SEQ ID NO: 2 that is identical to instant SEQ ID NO: 3 on p. 2, line 3 and p. 11, lines 18-26. Fusion proteins are taught on p. 13, lines 16-36.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. There is no mention of serum amyloid A protein in the specification as filed.

7. Claims 43-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art and the breadth of the claims. *Ex Parte Forman*, (230 USPQ 546 (Bd Pat. App. & Int. 1986)); *In re Wands*, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

These claims are drawn to methods of inhibiting IL-TIF-induced proliferation of hematopoietic cells. The specification teaches on p. 60, lines 5-7, that IL-TIF is inhibitory, rather than proliferative. Thus the skilled artisan would not expect inhibiting its action to have the desired result. Thus, without further guidance, it would require undue experimentation for the skilled artisan to practice the invention.

7. Claims 46-60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

These claims are drawn to methods of treating inflammatory conditions or suppressing immune responses by inhibiting IL-TIF. The specification teaches that IL-TIF binds to zcytor11 and has pro-inflammatory effects (p. 60, lines 13-15). The specification further teaches that IL-TIF decreases the level of lymphocytes and red blood cells *in vivo* (p. 60, lines 5-7) and inhibits proliferation or growth of stem cells (p. 60, lines 19-25). However, there are no teachings as to when IL-TIF is produced, and thus when administration of soluble zcytor11 would be expected to be beneficial. There is further no guidance to indicate in which diseases IL-TIF “plays a role”, to indicate that the diseases specified in claims 56 and 58 involve IL-TIF. Tissue distribution of the receptor, as taught on p. 60, lines 12-18, and the statement that IL-TIF “could play a role” in disease is not sufficient guidance to identify to one of skill in the art which diseases involve IL-TIF. What is need are teachings to indicate that IL-TIF itself is associated with particular conditions, and what those particular conditions are. Without further guidance to indicate what proteins, if any, are affected by IL-TIF, and in what diseases it is involved, it would require undue experimentation for the skilled artisan to practice the invention as broadly claimed. There are also no teachings provided to indicate that antibody production of any kind, as claimed in claims 47-50, or production of serum amyloid A, as claimed in claims 51-53, would be affected or could be linked to inhibition of IL-TIF. No working examples are provided and there are no compensatory examples in the prior art and there is no other guidance to indicate to the skilled artisan that the methods could be practiced as claimed.

NO CLAIM IS ALLOWED.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
2 March 2004



JANET ANDRES
PATENT EXAMINER